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| 10/505,272 | 08/20/2004 | Stephen Kerr | 127272.00111 | 5520 |
| 21369 7590 03/15/2010 PEPPER HAMILTON LLP ONE MELLON CENTER, 50TH FLOOR 500 GRANT STREET PITTSBURGH, PA 15219 | | | EXAMINER RYCKMAN, MELISSA K | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,272

Applicant(s)

KERR, STEPHEN

Examiner

MELISSA RYCKMAN

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 and 7-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This office action is in response to claims filed 12/17/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (U.S. Patent No. 5,860,991) and further in view of Gordon (U.S. Patent No. 5,741,277).

Klein teaches a device for fashioning a closure of a puncture site in an issue comprising:

- a cannula member (S) having proximal and distal ends and a lumen
- a connecting rod (14) disposed axially within said cannula, said connecting rod having a proximal end oriented towards said proximal end of said cannula and a distal end oriented toward said distal end of said cannula, said connecting rod having an actuating mechanism operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula (60)
- a needle/suture (20 and 30) complex mounted upon said distal end of said connecting rod (14), said needle/suture complex comprising at least one pair of angled needles (20) each of said angled needles having a needle tip and having

a suture extending therebetween (Fig. 11), said needle/suture complex further comprising two or more needle holder arms (slots in 22 for 20, Fig. 8) each of said needle holder arms receiving an angled needle, the needle holder arms are directly connected to the distal end of the connecting rod (14, connected Fig. 11, the arms are directly connected via 46, similarly to the current application using a pin to directly connect the arms to the connecting rod)

- wherein said angled needles(20) are capable of traversing at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula (Figs. 8 and 9)
- a needle trap mechanism (42) disposed within the lumen of said cannula and positioned axially about the connecting rod, operative to lockingly engage the needle tips of said angled needles of said needle/suture complex after said needle holder arms assume the second operative configuration (Fig. 9)
- wherein said needle trap mechanism (42) is operative to draw said angled needles and said needle tips proximally into the lumen of said cannula causing said angled needles to dislodge from a needle holder arms and advance upwardly through the cannula (Fig. 10) with suture ends remaining attached thereto such that the device may be withdrawn from the puncture site with the suture extending between the needles, forming a closure of said puncture site
- said angled needles (20) are further operative to assume one or both of the following additional configurations: a folded configuration wherein said angled needles are operative to extend through the lumen of said cannula (Fig. 7); and a

retracted configuration wherein said angled needles are biased inwardly toward the lumen of said cannula (Fig. 9)

- the distal end of said cannula (S) is positionable through a puncture site in a tissue (Fig. 7)
- a handle formed upon said cannula (Fig. 6)
- a trigger (60) formed upon the proximal end of said connecting rod and operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula (Fig. 6)
- said handle (58) and said trigger (60) are positioned relative to one another to enable the handle to be grasped and the trigger to be manipulated by a single hand of a user (Fig. 6)
- a tapered mount (22 and 46 combined) formed at said distal end of said connecting rod wherein said needle/suture complex is positioned upon said tapered mount, and where the tapered mount having a generally hourglass shape (between 46 and 22, Fig. 2).
- said needle trap mechanism (42) further comprises a cylindrical sleeve (42) axially mounted about said connecting rod and said cannula, said needle trap mechanism (42) having a proximal end with a lever formed thereon (44, Fig. 5) and a distal end having a needle catch formed therein, said needle catch being operative to lockingly engage with said angled needles of said needle/suture complex after said needle holder arms assume said second operative configuration (Fig. 9)

- said lever (44) formed upon said needle trap mechanism is operative to cause said needle trap mechanism to extend distally and retract proximally within the said cannula
- said needle trap mechanism, when lockingly engaged with said needle tips of said angled needles, disengages said angled needles from said needle holder arms and then captures said angled needles within said cannula when said needle trap mechanism retracts proximally within said cannula (capable of being used as described)

Klein teaches the claimed invention but does not teach the details of the needle holder arms as described in the claims; however Gordon teaches said needle holder arms (64a, 64b in Figs. 4A and 4B) being angled (Gordon, with respect to each other in Fig. 30B) and connected to the distal end of said connecting rod, said connecting rod operative to pivot the needle holder arms (Gordon, 64a, 64b in Fig. 30B) between a first operative configuration (Gordon, Fig. 29) wherein said needle holder arms extend in opposed directions from the distal end of said cannula and a second operative configuration (Gordon, Fig. 30B) wherein said needle holder arms are biased inwardly relative to said first operative configuration each respective one of said pair of needle holder arms are biased to extend across said puncture site as said needle holder arms assume said first operative configuration. It would have been obvious to one of ordinary skill in the art to use the needle arms of Gordon with the device of Klein, as this provides a proper placement of the needles for closing a fascia wound.

Response to Arguments

Applicant's arguments filed 12/17/09 have been fully considered but they are not persuasive. The applicant generally argues:

- Gordon fails to teach "needle holder arms being angled and directly connected to the distal end of said connecting rod"
- Neither Klein nor Gordon teach that both the needles and the needle holder arms have bends.

The examiners position is Klein teaches that the needle holder arms are directly connected to the distal end of the connecting rod (14, connected, Fig. 11, the arms are directly connected via 46, similarly to the current application, using a pin to directly connect the arms to the connecting rod). As stated in the above rejection, Klein teaches needles with bends, and Gordon teaches needle holder arms with bends, and the 103 rejection combines these elements.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MKR
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Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773